

## Definitions—Preamble

### National Organic Program Overview

#### Subpart A - Definitions

##### Description of Regulations

This subpart defines various terms used in this part. These definitions are intended to enhance conformance with the regulatory requirements through a clear understanding of the meaning of key terms.

We have amended terms and definitions carried over from the proposed rule where necessary to make their wording consistent with the language used in this final rule. We have revised the definitions of the following words for greater clarity: person, practice standard, inert ingredient, processing, tolerance. We have removed the definitions for the following terms because the terms are not used in this final rule or have been determined to be unnecessary: accredited laboratory, estimated national mean, system of organic production and handling. We received comments on some of these definitions that have been deleted. We have not addressed those comments here because the relevant definitions have been deleted.

##### Definitions - Changes Based on Comments

This subpart differs from the proposed rule in several respects as follows:

(1) Many commenters requested changes to the definition of "excluded methods." Comments included requests to use the more common term, "genetically modified organisms(GMO)"; to include the products of excluded methods/GMO's in the definition; to more closely follow the NOSB definition by adding gene deletion, doubling, introduction of a foreign gene, and changing gene position; to include that excluded methods are prohibited by the Act and by the regulations in this part; to change the wording of the reference to "recombinant DNA"; and to add that the definition of excluded methods only covers "intentional use."

We have accepted some of the comments and have modified the definition accordingly. Specifically, we have included reference to the "methods"-gene deletion, gene doubling, changing positions of genes, and introducing foreign genes-that were included in the original NOSB definition. This will make the definition even more closely parallel the NOSB recommendation. We also refer to recombinant DNA technology, which is technically more accurate than the proposed rules reference to recombinant DNA as a "method."

We have not accepted the comments that requested adding the products of excluded methods to the definition. The emphasis and basis of these standards is on process, not product. We have specifically structured the provisions relating to excluded methods to refer to the use of methods. Including the products of excluded methods in the definition would not be consistent with this approach to organic standards as a process-based system. For the same reason, we have retained the term, "excluded methods," to reinforce that process-based approach.

We have also rejected comments requesting that we include the prohibition on excluded methods in the definition and, likewise, those requesting that we refer to "intentional use" of excluded methods. The final rule maintains and clarifies the prohibition on the use of excluded methods in organic production systems. The prohibition is most properly addressed

in the appropriate provisions of the regulations, particularly in Section 205.105, and not in the definition. Similarly, although we recognize that a distinction between intentional and unintentional use of excluded methods may be meaningful, particularly as it pertains to issues of drift, this is an issue that is best handled in the sections of the regulation governing use of excluded methods, not in the definition. The definition for "excluded methods" now reads:

A variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include cell fusion, microencapsulation and macroencapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the position of genes when achieved by recombinant DNA technology). Such methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture."

(2) Many commenters objected to the definition of "compost" in the proposed rule because it required that compost must be produced in a facility that was in compliance with the Natural Resource Conservation Service's (NRCS) practice standard for a composting facility. We agree with these commenters and removed the requirement to comply with the NRCS practice standard. However, the final rule incorporates new requirements for the production of compost that are included in the definition. The final rule requires that compost must be produced through a process that combines plant and animal materials with an initial C:N ratio of between 25:1 and 40:1. Furthermore, producers using an in-vessel or static aerated pile system must maintain the composting materials at a temperature of between 131F and 170F for 3 days. Producers using a windrow system must maintain the composting materials at a temperature between 131F and 170F for 15 days, during which time, the materials must be turned a minimum of five times. We developed the requirements in the final rule for producing an allowed composted material by integrating standards used by the Environmental Protection Agency (EPA) and USDA's Natural Resources Conservation Service (NRCS). The requirements for the carbon-to-nitrogen (C:N) ratio for composting materials is the same as that found in the NRCS practice standard for a composting facility. The time and temperature requirements for in-vessel, static aerated pile, and window composting systems are consistent with those which EPA regulates under 40 CFR 503 for the production of Class A sewage sludge. Additionally, AMS reviewed these compost production requirements with USDA's Agricultural Research Service (ARS). This subject is discussed further under subpart C, Crop Production, Changes Based on Comment.

(3) Some commenters stated that allowing nonagricultural or synthetic substances as feed supplements contradicted the definition for "feed supplement" in the proposed rule. These commenters stated that the definition stipulated that a feed supplement must, itself, be a feed material and that the proposed definition for "feed" did not include nonagricultural or synthetic substances. These commenters stated that the definition of "feed supplement" needed to be amended to accommodate nonagricultural or synthetic substances, or such substances should not be allowed. We agree with these commenters and amended the definition for "feed supplement" to read "a combination of feed nutrients added to livestock feed to improve the nutritional balance or performance of the total ration." One commenter recommended modifying the definition of "feed additive" to "a substance added to feed in micro quantities to fulfill a specific nutritional need; i.e., essential nutrients in the form of amino acids, vitamins, and minerals." We agree that this modification provides a more precise description of "feed additive" and have included the change. The changes to the definitions for "feed supplement" and "feed additive" are further discussed under item (4) of Livestock Production - Changes Based on Comments.

(4) One commenter stated that the definition for "forage" inaccurately described it as

"vegetable matter," and suggested that "vegetative matter" was a more suitable description. We agree with the suggestion and have incorporated the change.

(5) Some commenters stated that the definition for "mulch" implied that all mulch materials must either be organic or included on the National List. These commenters maintained that, if this was the intent of the proposed rule, the provision was too restrictive. They recommended revising the definition to clarify that natural but nonorganic plant and animal materials, if managed to prevent contamination from prohibited substances, could be used as mulch without being added to the National List. This was the intent in the proposed rule, and we have modified the definition to make this provision clearer.

(6) Many commenters stated that the final rule should include a definition of "organic production" that required that certified operations must preserve or protect biodiversity. These commenters stated that the preservation of biodiversity is a requirement in many existing organic certification standards, including the Codex guidelines. They also stated that the NOSB had included the requirement to preserve biodiversity in its definition of organic. We agree with the intent of these comments but prefer the term, "conserve," to "preserve" because it reflects a more dynamic, interactive relationship between the operation and biodiversity over time. We included a definition for organic production as "a production system that is managed in accordance with the Act and regulations in this part to respond to site-specific conditions by integrating cultural, biological, and mechanical practices that foster cycling of resources, promote ecological balance, and conserve biodiversity." We deleted the definition for "organic system of production and handling" in the final rule.

(7) Several commenters, including the NOSB, were concerned that the definition for "planting stock" as "any plant or plant tissue, including rhizomes, shoots, leaf or stem cuttings, roots, or tubers, used in plant production or propagation" was sufficiently broad to be applied to annual seedlings. We agree that it is important to establish that annual seedlings are not covered by the definition of "planting stock" and amended the definition to exclude them. The definition for planting stock in the final rule states "any plant or plant tissue other than annual seedlings but including rhizomes, shoots, leaf or stem cuttings, roots, or tubers, used in plant production or propagation." The final rule retains the definition for "annual seedling" from the proposed rule.

(8) Several commenters recommended that the definition of "processing" should be amended to include "distilling" as an allowed practice. We agree with this comment and added distilling as an allowed processing practice.

(9) Several commenters recommended that the final rule include a definition for "processing aid" that is consistent with the definition proposed by the NOSB and used by the Food and Drug Administration (FDA). We agree with these commenters and have included a definition for processing aid that is the same as the definition used by FDA and found in 21 CFR Part 101.100(a)(3)(ii).

(10) Many commenters questioned whether the term, "State organic certification program," in the proposed rule included organic programs from States that did not offer certification services. These commenters stated that the final rule should include provisions for all State organic programs regardless of whether they functioned as certifying agents. We agree with these commenters and have amended the final rule by incorporating the term, "State organic program," as "a State program that meets the requirements of section 6506 of the Act, is approved by the Secretary, and is designed to ensure that a product that is sold or labeled as organically produced under the Act is produced and handled using organic methods." The term, "State organic program," encompasses such programs whether they offer certification services or not.

(11) One commenter stated that the definition for "wild crop" only referred to a plant or part of a plant that was harvested from "an area of land." This commenter was concerned that the definition would preclude the certification of operations that produce wild aquatic crops, such as seaweed, and stated that the OFPA does allow for certifying such operations. We agree with this commenter and changed the definition to refer to a plant or part of a plant harvested from a "site."

(12) Many commenters stated that the soil fertility and crop nutrient management practice standard lacked a definition for "manure." These commenters maintained that the different provisions contained in the practice standard for "manure" and "compost" would be difficult to enforce without clear definitions to differentiate between the two materials. We agree with these comments and added a definition for manure as "feces, urine, other excrement, and bedding produced by livestock that has not been composted."

(13) Some commenters stated that the National List in the final rule should include an annotation for narrow range oils to limit their use to a specific subset of such materials recommended by the NOSB. We agree with this comment but, rather than add an annotation, we have included the specifications recommended by the NOSB in a new definition for narrow range oils. Narrow range oils are defined as "petroleum derivatives, predominately of paraffinic and naphthenic fractions with a 50-percent boiling point (10 mm Hg) between 415F and 440F.

(14) Many commenters maintained that the final rule needed a definition of the term, "pasture," to describe the relationship between ruminants and the land they graze. These commenters stated that a meaningful definition of "pasture" must incorporate the nutritional component that it provides livestock, as well as the necessity to manage the land in a manner that protects the natural resources of the operation. We agree with these commenters and have added a definition of "pasture" as "land used for livestock grazing that is managed to provide feed value and maintain or improve soil, water, and vegetative sources."

(15) Many commenters stated that a definition for "split operation" was necessary to prevent commingling between organic and nonorganic commodities on operations that produced or handled both forms of a commodity. We agree with these comments and have included a definition for "split operation" as "an operation that produces or handles both organic and nonorganic agricultural products."

### **Definitions - Changes Requested But Not Made**

This subpart retains from the proposed rule terms and their definitions on which we received comments as follows:

(1) Many commenters objected to the definition of "sewage sludge" because it excluded ash generated in a sewage sludge incinerator and grit and screenings generated during preliminary treatment of domestic sewage in treatment works. We have not changed the definition for "sewage sludge" because it provides the most comprehensive and enforceable description of the types of materials that commenters wanted to prohibit. The definition for "sewage sludge" in the proposed rule arose in response to significant public comment on the first proposed rule for national organic standards (62 Federal Register, No. 241) that recommended prohibiting biosolids in organic production. When incorporating those comments into the proposed rule, we did not use the term, "biosolids," because it does not have a standardized definition under Federal regulations. The term, "biosolids," is commonly used to refer to "sewage sludge," which is the regulatory term established in 40 CFR Part 503. We incorporated the precise definition from 40 CFR Part 503, even though it does not

include ash, grit, or screenings, because it provided the clearest description of the types of materials identified in public comment.

While commenters are correct that ash, grit, or screenings from the production of sewage sludge are not prohibited by this definition, these materials are prohibited elsewhere in the regulation. The soil fertility and crop nutrient management practice standard in section 205.203 establishes the universe of allowed materials and practices. These allowed materials and practices are crop rotations, cover crops, plant and animal materials (including their ash), nonagricultural, natural materials, and, under appropriate conditions, mined substances of low and high solubility and synthetic materials included on the National List. Ash, grit, or screenings from the production of sewage sludge cannot be included in any of these categories and, therefore, cannot be used in organic production. We retained the definition of "sewage sludge" because it most clearly conveys the wide array of commercially available soil amendments that might be considered for organic production but that the final rule expressly prohibits. We have not added specific exclusions for sewage sludge, ash, grit, or screenings because these materials are prohibited through other provisions in the practice standard.

(2) The proposed rule prohibited the handler of an organic handling operation from using ionizing radiation for any purpose. The vast majority of commenters agreed with this prohibition and further recommended that the term, "ionizing radiation," should be defined to identify the specific applications that are prohibited. Most commenters supported a definition based on the FDA requirements in 21 CFR part 179.26 for the treatment or processing of food using ionizing radiation. While agreeing with the prohibition on ionizing radiation, these commenters favored allowing certain forms of irradiation such as the use of X-rays to inspect for debris such as stones that were inadvertently commingled with organically handled food. Other commenters recommended a prohibition on all forms of irradiation, which would include X-rays for inspection purposes, ultraviolet light, and microwaves in addition to ionizing radiation. Finally, a number of commenters stated that ionizing radiation is a safe and effective process for handling food and, therefore, should not be prohibited in organic handling.

We have not added a definition for "ionizing radiation" to the final rule because we have incorporated specific references to the applications that are prohibited in the regulatory text. The final rule prohibits the handler of an organic handling operation from using ionizing radiation as specified under 21 CFR part 179.26. These are the FDA-approved uses of ionizing radiation that commenters most frequently recommended that we prohibit in organic handling operations. They include the use of cobalt-60, cesium-137, and other sources of radiation for the purpose of controlling microbial contaminants, pathogens, and pests in food or to inhibit the growth and maturation of fresh foods. At its June 2000 meeting, the NOSB recommended prohibiting ionizing radiation for the purpose of controlling microbial contaminants, pathogens, parasites, and pests in food, preserving a food, or inhibiting physiological processes such as sprouting or ripening. The final rule does not prohibit the handler of an organic handling operation from using the FDA-approved applications of X-rays for inspecting food. The prohibition on ionizing radiation in the final rule is based solely on consumer preference as reflected in the overwhelming public comment stating that organically handled foods should not be treated in that manner.

(3) Some commenters recommend that the final rule incorporate definitions for the terms, "food additives," "extraction methods," "incidental additive," and "substantially transform." However, these terms are not used in the final rule and do not require a definition.

## **Definitions - Clarifications**

Following our review of the definitions provisions in the proposed rule, we decided to further

clarify the following provision in the final rule:

We were concerned that "State entity," the meaning of which encompasses both domestic and foreign political subdivisions, may be confused with "State," the meaning of which is limited to the States of the United States, its territories, the District of Columbia, and Puerto Rico. To avoid any possible confusion as to which provisions in this final rule apply to States and which apply to the broader political subdivisions, we have replaced the term, "State entity," with the term, "governmental entity," while retaining the same definition language in the proposed rule.